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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/035,783	12/24/2001	Michael Graupc	1016US	3968

7590 06/10/2004

Celera, An Appera Corporation Business
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EXAMINER

SHIAO, REI TSANG

ART UNIT

PAPER NUMBER

1626

DATE MAILED: 06/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/035,783	GRAUPE ET AL.	
Period for Reply	Examiner	Art Unit	
	Robert Shiao	1626	
<i>-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --</i>			
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.			
<ul style="list-style-type: none"> - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). 			
Status			
1) <input checked="" type="checkbox"/> Responsive to communication(s) filed on <u>responses filed on 3/29, 2004</u> .			
2a) <input checked="" type="checkbox"/> This action is FINAL. 2b) <input type="checkbox"/> This action is non-final.			
3) <input type="checkbox"/> Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.			
Disposition of Claims			
4) <input checked="" type="checkbox"/> Claim(s) <u>1-29 and 31</u> is/are pending in the application.			
4a) Of the above claim(s) <u>29 and 31</u> is/are withdrawn from consideration.			
5) <input type="checkbox"/> Claim(s) _____ is/are allowed.			
6) <input checked="" type="checkbox"/> Claim(s) <u>10</u> is/are rejected.			
7) <input checked="" type="checkbox"/> Claim(s) <u>1-9 and 11-28</u> is/are objected to.			
8) <input type="checkbox"/> Claim(s) _____ are subject to restriction and/or election requirement.			
Application Papers			
9) <input type="checkbox"/> The specification is objected to by the Examiner.			
10) <input type="checkbox"/> The drawing(s) filed on _____ is/are: a) <input type="checkbox"/> accepted or b) <input type="checkbox"/> objected to by the Examiner.			
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).			
11) <input type="checkbox"/> The proposed drawing correction filed on _____ is: a) <input type="checkbox"/> approved b) <input type="checkbox"/> disapproved by the Examiner.			
If approved, corrected drawings are required in reply to this Office action.			
12) <input type="checkbox"/> The oath or declaration is objected to by the Examiner.			
Priority under 35 U.S.C. §§ 119 and 120			
13) <input type="checkbox"/> Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).			
a) <input type="checkbox"/> All b) <input type="checkbox"/> Some * c) <input type="checkbox"/> None of:			
1. <input type="checkbox"/> Certified copies of the priority documents have been received.			
2. <input type="checkbox"/> Certified copies of the priority documents have been received in Application No. _____.			
3. <input type="checkbox"/> Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).			
* See the attached detailed Office action for a list of the certified copies not received.			
14) <input checked="" type="checkbox"/> Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).			
a) <input type="checkbox"/> The translation of the foreign language provisional application has been received.			
15) <input type="checkbox"/> Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.			
Attachment(s)			
1) <input type="checkbox"/> Notice of References Cited (PTO-892)		4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ .	
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)		5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)	
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>0604</u> .		6) <input type="checkbox"/> Other: _____ .	

DETAILED ACTION

1. This application claims benefit of the provisional application:
60,257,603 with a filing date 12/22/2000.
2. Cancellation of claim 30 in Paper No. 9003, dated September 15, 2003, is acknowledged. Claims 1-29, and 31 are pending in the application.

Responses to Election/Restriction

3. Applicant's election of restriction requirement II with traverse of Group I claims 1-28, in part, in Paper No. 0304, dated March 29, 2004, is acknowledged. The traversal is on the grounds that the Examiner has not offered any explanation of restriction requirement II, and *In re Harnish* and *Ex parte Hozumi* are cited. This is not found persuasive and reasons are given, *infra*.

Status of the Claims

4. It is noted that it is impossible for the examiner to discover instant formula (I) without limiting the number of compounds to be considered via a proper restriction requirement. The simplest compound encompassed by the claims appears to be $(\text{H}_2\text{NCH}_2)_2\text{CH-C(O)-NH-CF}_2\text{CHO}$ which includes the CH-C(O)-NH- core. Many more complicated structures, including many with heterocyclic rings are encompassed by the generic structure of claim 1 and have no relationship with or apparent common activity with this simplest compound. Applicants' claims are especially confusing as all of the three main variables are defined by a second set of variables which include further

variables which include additional variables, see petition decision, dated December 3, 2003, page 3, lines 11-17.

5. Claims 1-29, and 31 are pending in the application. The scope of the invention of the elected subject matter is as follows:

Claims 1-28, in part, drawn to compounds/compositions of formula (I) having variables X_1 , R^3 , and R^4 . X_1 represents $-C(R^1)(R^2)X^2$, wherein X^2 is as defined in claim 1, wherein hetero(C₄-C₁₀)aryl or hetero(C₄-C₁₀)cycloalkyl of X^2 represents pyran, thiopyran, pyrimidine, thiazole, isothiazole, pyridine, furan, imidazole, isoxazole, oxadiazole, oxazole, or triazole thereof; R^1 and R^2 are as defined in claim 1, except: R^1 and R^2 independently do not represent heteroaryl, heterocycloalkyl, or heterocycloalkylene or R^1 and R^2 independently is not substituted with heteroaryl, heterocycloalkyl, or heterocycloalkylene, R^1 and R^2 taken together with the carbon atom do not form hetero(C₃-C₈)cycloalkylene; R^3 represents $-C(R^{16})(R^{17})X^7$, R^{16} and R^{17} independently represent hydrogen, alkyl, fluoro, or hydroxy; X^7 is as defined in claim 1 except: X^7 do not represent heteroaryl, heterocycloalkyl, or heterocycloalkylene, and X^7 is not substituted with heteroaryl, heterocycloalkyl, or heterocycloalkylene; and R^4 represents $-C(R^{16})(R^{17})X^7$, R^{16} and R^{17} independently represent hydrogen, alkyl, fluoro, or hydroxy; X^7 represents $-R^{15}$, $-X^4OR^{15}$, $-X^4SR^{15}$, $-X^4S(O)R^{15}$, $-X^4S(O)_2R^{15}$, $-X^4C(O)R^{15}$, $-X^4C(O)OR^{15}$, $-X^4OC(O)R^{15}$, $-X^4NR^{15}R^{12}$, $-X^4NR^{12}C(O)R^{15}$, $-X^4NR^{12}C(O)OR^{15}$, $-X^4NC(O)NR^{15}R^{12}$, $-X^4NR^{12}S(O)_2R^{15}$, $-X^4NR^{12}C(O)NR^{15}R^{12}$, or $-X^4NR^{12}C(NR^{12})NR^{15}R^{12}$, and X^4 represents a bond or alkylene, R^{12} represents

hydrogen or alkyl, R¹⁵ is as defined in claim 1 except: wherein R¹⁵ does not represent hetero(C₅-C₁₀)aryl(C₀-C₆)alkyl or hetero(C₈-C₁₂)bicycloaryl(C₀-C₆)alkyl, and wherein the hetero(C₃-C₁₀)cycloalkyl of R¹⁵ represents **morpholinyl** thereof, and X⁷ is not substituted with heteroaryl, heterocycloalkyl, or heterocycloalkylene.

The above mentioned withdrawn compounds which are withdrawn from consideration as being for non-elected subject matter differ materially in structure and composition from the compounds of the elected invention. The withdrawn compounds contain varying functional groups (i.e., heterocyclic or heteroaryl) which differ from those of the elected invention such as azepane, piperidine, pyran, piperazine, morpholine, pyridazine, pyrimidine, thiazole, oxazole, etc, which are chemically recognized to differ in structure and function. This recognized chemical diversity of the functional groups can be seen by the various classification of these functional groups in the U.S. classification system, i.e., class 540 subclass 484(+) (azepane), class 546 subclass 184(+) (piperidine), class 549 subclass 200(+) (pyran), class 544 subclass 358(+) (piperazine), class 544 subclass 106(+) (morpholine), class 544 subclass 224 (+) (pyridazine), class 544 subclass 242 (+) (pyrimidine), class 548 subclass 146(+) (thiazole), class 548 subclass 215(+) (oxazole), etc. Therefore, again, the compounds which are withdrawn from consideration as being for non-elected subject matter differ materially in structure and composition and have been restricted properly.

The Markush group set forth in the claims includes both independent and distinct inventions, and patentably distinct compounds (or species) within each invention. However, this application discloses and claims a plurality of patentably distinct

inventions far too numerous to list individually. Moreover, each of these inventions contains a plurality of patentably distinct compounds, also far too numerous to list individually. For these reasons provided below, restriction to one of the following Groups is required under 35 U.S.C. 121, wherein an Group is a set of patentably distinct inventions of a broad statutory category (e.g. Compounds, Methods of Use, Methods of Making, etc.).

Moreover, the examiner must perform a commercial database search on the subject matter of each group in addition to a paper search, which is quite burdensome to the examiner.

The invention claims 1-28, in part, embraced in above elected subject matter are prosecuted in the case. Claims 1-28, in part, not embraced in above elected subject matter, and claims 29 and 31, are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention.

The requirement is still deemed proper and is therefore made FINAL.

Responses to Amendment

6. Since claim 30 has been cancelled, therefore, the rejection of claim 30 under 35 U.S.C. 101 in Paper No. 0603, dated June 03, 2003, is obviated.
7. Since a terminal disclaimer against the copending application No. 10/183,128 has not been filed, therefore, the provisionally rejection of claim 10 under obviousness-type double patenting is maintained, see the paragraph 6 of Paper No. 0603, dated June 03, 2003.

Objection

8. Claims 1-28 are objected to as containing non-elected subject matter (i.e., heterocyclic or heteroaryl of variables R¹, R², X⁷, and R¹⁵, etc). It is suggested that applicants amend the claims to the scope of the elected subject matter as defined on pages 3-4 *supra*.

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Shiao whose telephone number is (571) 272-0707. The examiner can normally be reached on 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be reached on (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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June 8, 2004